

Women, Minorities, & Children in Clinical Research



Inclusion of Women and Minorities in Clinical Research

- 1986 Inclusion of women encouraged
- 1987 Inclusion of minorities encouraged
- 1993 NIH Revitalization Act
- 1994 NIH revised inclusion policy to mandate that women & minorities **MUST** be included in all clinical research studies

Phase III Clinical Trial Plans

- Investigators must review data for potential sex/gender or race/ethnicity differences that may be experienced in the trial.
- Phase III trials are required to include sufficient entry of both genders and racial/ethnic participants to perform a valid analysis of the intervention effects.

Evaluate Recruitment Plans

- Do investigators address both genders and minorities being recruited?
- Do investigators have access to recruit these populations in the numbers they plan?
- Do the investigators adequately list how they will recruit in a timely fashion?

Inclusion of Children

- 1996 NIH Workshop
- 1998 New policy to include children



Investigators must include a section that outlines their plans to include or exclude children in their study, along with sufficient rationale.

Women, Minorities, & Children in Research: More Information

- NIH Women & Minority Outreach Notebook:
<http://www4.od.nih.gov/orwh/outreach.pdf>
- NIH Policy on Inclusion of Women & Minorities
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>
- NIH Policy on Inclusion of Children
<http://grants.nih.gov/grants/guide/notice-files/not98-024.html>